

K955365

**Compact Cotrel-Dubousset (CCD™) Spinal System
510(k) Summary**

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- I. **Company:** Sofamor Danek USA
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- II. **Proprietary Trade Name:** Compact Cotrel-Dubousset (CCD™) Spinal System

Classification Name: Pedicle Screw Fixation - Spondylolisthesis spinal fixation device system. Otherwise, spinal interlaminar fixation orthosis.

- III. The CCD™ Spinal System consists of rods, hooks, screws, connectors, cross connectors, and other components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components. The purpose of the CCD™ Spinal System is to provide stabilization during the development of a solid spinal fusion. The CCD™ Spinal System implant components are fabricated either from ASTM F138 or its ISO equivalent stainless steel or titanium alloy conforming to ASTM F136 or its ISO equivalent (non-pedicle screw indications only) and may be sold sterile or non-sterile. Stainless steel implants are not to be used with titanium alloy implant components in a spinal construct.
- IV. The CCD™ Spinal System is limited to non-cervical use in the posterior spine. The CCD spinal screws, when used as pedicle screws with the CCD™ Spinal System, are intended only for patients: (a) having severe spondylolisthesis (grade 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. When used for pedicle screw fixation as described above, the screws are indicated only for insertion no higher than L3 and no lower than the sacrum. Otherwise, the CCD screws, when used in posterior fixation, are intended for sacral/iliac attachment only. Except for situations where stainless steel screws are attached to the pedicles of the lumbar and sacral spine via a posterior surgical approach in a CCD construct for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the L5-S1 vertebral joint, the specific indications for the CCD Spinal System (either stainless steel or titanium alloy versions) are the following:

1. Degenerative disc disease (as defined by instability in the presence of one or more of the following: osteophyte formation, decrease in disc space height, endplate sclerosis, disc herniations, facet joint changes, and scarring and/or thickening of the annulus fibrosis, ligamentum flavum, or facet joint capsule).
2. Pseudoarthrosis
3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, and lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

All of the CCD hooks are intended for posterior thoracic and/or lumbar use only. CCD cross connectors are intended for posterior thoracic, lumbar, and/or sacral use only.